# Complete Summary

## GUIDELINE TITLE

Preterm prelabour rupture of membranes.

## BIBLIOGRAPHIC SOURCE(S)

Royal College of Obstetricians and Gynaecologists (RCOG). Preterm prelabour rupture of membranes. London (UK): Royal College of Obstetricians and Gynaecologists (RCOG); 2006 Nov. 11 p. (Guideline; no. 44). [66 references]

## GUIDELINE STATUS

This is the current release of the guideline.

## COMPLETE SUMMARY CONTENT



## SCOPE

### DISEASE/CONDITION(S)

Preterm rupture of membranes in pregnancy

### GUIDELINE CATEGORY

Diagnosis
Evaluation
Management
Risk Assessment

### CLINICAL SPECIALTY

Family Practice
Obstetrics and Gynecology

## INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Nurses
Physician Assistants
Physicians

## GUIDELINE OBJECTIVE(S)

To make recommendations relating to the diagnosis, investigation, and management of women with preterm prelabour rupture of the membranes (PPROM)

## TARGET POPULATION

Pregnant women with preterm prelabor rupture of the membranes

## INTERVENTIONS AND PRACTICES CONSIDERED

### Diagnosis/Evaluation

1. Maternal history
2. Sterile speculum examination
3. Ultrasound examination
4. Fetal monitoring using cardiotocography

**Note**: The following were considered but not recommended: digital examination, biophysical profile scoring, Doppler velocimetry, routine amniocentesis

### Management/Treatment

1. Antibiotic prophylaxis (erythromycin)
2. Antenatal corticosteroids
3. Selection of patients for outpatient monitoring
4. Consideration of gestational age for delivery

**Note**: The following were considered but not recommended: co-amoxiclav, prophylactic tocolysis, transvaginal or transabdominal amnioinfusion in labor

## MAJOR OUTCOMES CONSIDERED

- Incidence of preterm prelabor rupture of membranes (PPROM)
- Perinatal mortality and morbidity
- Delay in delivery following PPROM
- Maternal and fetal complications associated with PPROM

# METHODOLOGY

## METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

## DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The Cochrane Library (including the Cochrane Database of Systematic Reviews, DARE, and EMBASE), TRIP, Medline, and PubMed (electronic databases) were searched for relevant randomised controlled trials, systematic reviews, and meta-analyses. The search was restricted to articles published between 1966 and 2005. The databases were searched using the relevant Medical Subject Heading (MeSH) terms, including all subheadings, and this was combined with a keyword search. Search words included "preterm prelabour rupture of membranes," "amnioinfusion," "sealing amniotic membranes," "intra-amniotic infection," "Nitrazine," "fetal fibronectin," "amniocentesis," "antenatal corticosteroids," and "tocolytics," and the search limited to humans and English language. The National Library for Health and the National Guidelines Clearinghouse were also searched for relevant guidelines and reviews.

## NUMBER OF SOURCE DOCUMENTS

Not stated

## METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

## RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

### Levels of Evidence

**Ia**: Evidence obtained from meta-analyses of randomised controlled trials

**Ib**: Evidence obtained from at least one randomised controlled trial

**IIa**: Evidence obtained from at least one well-designed controlled study without randomisation

**IIb**: Evidence obtained from at least one other type of well-designed quasi-experimental study

**III**: Evidence obtained from well-designed non-experimental descriptive studies, such as comparative studies, correlation studies, and case studies

**IV**: Evidence obtained from expert committee reports or opinions and/or clinical experience of respected authorities

## METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review with Evidence Tables

## DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

## METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

## DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

## RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

The recommendations were graded according to the level of evidence upon which they were based. The grading scheme used was based on a scheme formulated by the Clinical Outcomes Group of the National Health Service Executive.

**Grade A** - Requires at least one randomised controlled trial as part of a body of literature of overall good quality and consistency addressing the specific recommendation. (Evidence levels Ia, Ib)

**Grade B** - Requires the availability of well controlled clinical studies but no randomised clinical trials on the topic of recommendations. (Evidence levels IIa, IIb, III)

**Grade C** - Requires evidence obtained from expert committee reports or opinions and/or clinical experiences of respected authorities. Indicates an absence of directly applicable clinical studies of good quality. (Evidence level IV)

## COST ANALYSIS

Published cost analyses were reviewed that evaluated the cost–effectiveness of aggressive tocolysis for premature labor associated with premature rupture of the membranes.

## METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

## DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Following discussion in the Guidelines and Audit Committee, each green-top guideline is formally peer reviewed. At the same time the draft guideline is published on the Royal College of Obstetricians and Gynaecologists Web site for further peer review discussion before final publication.

The names of author(s) and nominated peer reviewers are included in the original guideline document.

## RECOMMENDATIONS

### MAJOR RECOMMENDATIONS

*In addition to these evidence-based recommendations, the guideline development group also identifies points of best clinical practice in the original guideline document.*

Levels of evidence (**Ia-IV**) and grading of recommendations (**A-C**) are defined at the end of the "Major Recommendations" field.

**How Is the Diagnosis of Preterm Prelabour Rupture of Membranes (PPROM) Best Achieved?**

**B** - The diagnosis of spontaneous rupture of the membranes is best achieved by maternal history followed by a sterile speculum examination.

**C** - Ultrasound examination is useful in some cases to help confirm the diagnosis.

**C** - Digital examination should be avoided where PPROM is suspected.

**What Antenatal Tests Should Be Performed?**

**C** - Fetal monitoring using cardiotocography should be considered where regular fetal surveillance is required.

**B** - Biophysical profile scoring or Doppler velocimetry should not be considered as first-line surveillance or diagnostic tests for fetal infection.

The criteria for the diagnosis of clinical chorioamnionitis include maternal pyrexia, tachycardia, leucocytosis, uterine tenderness, offensive vaginal discharge, and fetal tachycardia. During inpatient observation, the woman should be regularly examined for such signs of intrauterine infection and an abnormal parameter or a combination of them may indicate intrauterine infection. The frequency of maternal temperature, pulse and fetal heart rate auscultation should be between 4 hours and 8 hours.

**What is the Role of Amniocentesis?**

**B** - Routine amniocentesis is not recommended for women with PPROM.

**Management**

**Are Prophylactic Antibiotics Recommended?**

**A** - Erythromycin (250 mg orally 6 hourly) should be given for 10 days following the diagnosis of PPROM.

**A** - Co-amoxiclav is not recommended for women with PPROM because of concerns about necrotising enterocolitis.

If group B streptococcus is isolated in cases of PPROM, antibiotics should be given in line with the recommendation for routine intrapartum prophylaxis in the National Guideline Clearinghouse (NGC) summary of the Royal College of Obstetricians and Gynaecologists (RCOG) Green-top Guideline No. 36: Prevention of Early Onset Neonatal Group B Streptococcal Disease.

**What is the Role of Antenatal Corticosteroids?**

**A** - Antenatal corticosteroids should be administered in women with PPROM.

**Tocolysis: Should Tocolytic Agents Be Used?**

**A** - Prophylactic tocolysis in women with PPROM without uterine activity is not recommended.

**Amnioinfusion**

**Should Amnioinfusion in Labour Be Carried Out?**

**A** - Transvaginal amnioinfusion in labour is not recommended for women with preterm rupture of membranes.

**B** - Transabdominal amnioinfusion is not recommended as a method of preventing pulmonary hypoplasia in very preterm PPROM.

**Use of Fibrin Glue**

**What is the Role of Fibrin Glue in the Sealing of Chorioamniotic Membranes to Prevent Pulmonary Hypoplasia?**

**B** - Fibrin sealants are not recommended as routine treatment for second-trimester oligohydramnios caused by PPROM.

**Outpatient Monitoring**

**Can Patients Be Monitored at Home?**

**B** - Women should be considered for outpatient monitoring of PPROM only after rigorous individual selection by a consultant obstetrician.

There are insufficient data to make recommendations of home, daycare and outpatient monitoring rather than continued hospital admission in women with PPROM. It would be considered reasonable to maintain the woman in hospital for at least 48 hours before a decision is made to allow her to go home. This method of management should be individualised and restricted to certain groups of women. Women should be instructed to take regular temperature recordings at

home every 12 hours or to be aware of the symptoms associated with infection. (Evidence level III)

**Delivery of the Fetus**

**When Is the Appropriate Time to Deliver?**

**B** - Delivery should be considered at 34 weeks of gestation.

**B** - Where expectant management is considered beyond 34 weeks of gestation, women should be counselled about the increased risk of chorioamnionitis and its consequences versus the decreased risk of serious respiratory problems in the neonate, admission for neonatal intensive care, and caesarean section.

**Definitions**:

**Grading of Recommendations**

**Grade A** - Requires at least one randomised controlled trial as part of a body of literature of overall good quality and consistency addressing the specific recommendation. (**Evidence levels Ia, Ib**)

**Grade B** - Requires the availability of well controlled clinical studies but no randomised clinical trials on the topic of recommendations. (**Evidence levels IIa, IIb, III**)

**Grade C** - Requires evidence obtained from expert committee reports or opinions and/or clinical experiences of respected authorities. Indicates an absence of directly applicable clinical studies of good quality. (**Evidence level IV**)

**Levels of Evidence**

**Ia**: Evidence obtained from meta-analyses of randomised controlled trials

**Ib**: Evidence obtained from at least one randomised controlled trial

**IIa**: Evidence obtained from at least one well-designed controlled study without randomisation

**IIb**: Evidence obtained from at least one other type of well-designed quasi-experimental study

**III**: Evidence obtained from well-designed non-experimental descriptive studies, such as comparative studies, correlation studies, and case studies

**IV**: Evidence obtained from expert committee reports or opinions and/or clinical experience of respected authorities

**CLINICAL ALGORITHM(S)**

None provided

## EVIDENCE SUPPORTING THE RECOMMENDATIONS

### TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations" field).

## BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

### POTENTIAL BENEFITS

Accurate diagnosis and appropriate management of preterm prelabor rupture of membranes

### POTENTIAL HARMS

Adverse drug effects

## QUALIFYING STATEMENTS

### QUALIFYING STATEMENTS

- These guidelines are "systematically developed statements which assist clinicians and patients in making decisions about appropriate treatment for specific conditions." Each guideline is systematically developed using a standardised methodology. Exact details of this process can be found in Clinical Governance Advice No. 1: Guidance for the Development of RCOG Green-top Guidelines (See the "Availability of Companion Documents" field in this summary.)
- These recommendations are not intended to dictate an exclusive course of management or treatment. They must be evaluated with reference to individual patient needs, resources and limitations unique to the institution and variations in local populations. It is hoped that this process of local ownership will help to incorporate these guidelines into routine practice. Attention is drawn to areas of clinical uncertainty where further research may be indicated.

## IMPLEMENTATION OF THE GUIDELINE

### DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

## INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

### IOM CARE NEED

Getting Better
Staying Healthy

### IOM DOMAIN

Effectiveness
Patient-centeredness

## IDENTIFYING INFORMATION AND AVAILABILITY

### BIBLIOGRAPHIC SOURCE(S)

Royal College of Obstetricians and Gynaecologists (RCOG). Preterm prelabour rupture of membranes. London (UK): Royal College of Obstetricians and Gynaecologists (RCOG); 2006 Nov. 11 p. (Guideline; no. 44). [66 references]

### ADAPTATION

Not applicable: The guideline was not adapted from another source.

### DATE RELEASED

2006 Nov

### GUIDELINE DEVELOPER(S)

Royal College of Obstetricians and Gynaecologists - Medical Specialty Society

### SOURCE(S) OF FUNDING

Royal College of Obstetricians and Gynaecologists

### GUIDELINE COMMITTEE

Guidelines and Audit Committee of the Royal College of Obstetricians and Gynaecologists

### COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

*Author*: Mr SGM Carroll, FRCOG, Dublin, Ireland

### FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Guideline authors are required to complete a "declaration of interests" form.

## GUIDELINE STATUS

This is the current release of the guideline.

## GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the Royal College of Obstetricians and Gynaecologists (RCOG) Web site.

Print copies: Available from the Royal College of Obstetricians and Gynaecologists (RCOG) Bookshop, 27 Sussex Place, Regent's Park, London NW1 4RG; Telephone: +44 020 7772 6276; Fax, +44 020 7772 5991; e-mail: bookshop@rcog.org.uk. A listing and order form are available from the RCOG Web site.

## AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Development of RCOG green-top guidelines: policies and processes. Clinical Governance Advice No 1a. 2006 Nov. Available from the Royal College of Obstetricians and Gynaecologists (RCOG) Web site.
- Development of RCOG green-top guidelines: producing a scope. Clinical Governance Advice No 1b. 2006 Nov. Available from the Royal College of Obstetricians and Gynaecologists (RCOG) Web site.
- Development of RCOG green-top guidelines: producing a clinical practice guideline. Clinical Governance Advice No 1c. 2006 Nov. Available from the Royal College of Obstetricians and Gynaecologists (RCOG) Web site.
- Searching for evidence. Clinical Governance Advice No 3. 2001 Oct. Available from the Royal College of Obstetricians and Gynaecologists (RCOG) Web site.

## PATIENT RESOURCES

None available

## NGC STATUS

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## COPYRIGHT STATEMENT



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